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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/467,368	12/20/1999	PETER KAMP HANSEN	4324.224-US	2312

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EXAMINER

RAO, MANJUNATH N

ART UNIT PAPER NUMBER

1652

DATE MAILED: 03/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/467,368

Applicant(s)

HANSEN ET AL.

Examiner

Manjunath N. Rao, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 08/886,765.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16. 6) ☐ Other:

DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1-16-03 has been entered.

Claims 54-71 are currently pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 54-65, 70 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 54-65, 70 are directed to animal feed compositions comprising a xylanase belonging to family 11, having a pH optimum in the range of 4.5-7.5 and a residual activity after incubation for 60 min at pH 6.0 of one or more of a) >96% residual activity when measured at 60° C, b) >83% activity when measured at 65° C, >20% activity when measured at 70° C and >10% activity when measured at 75° C, wherein such an enzyme is used in animal feed. Claims

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54-70 are rejected under this section of 35 USC 112 because the claims are directed to a feed composition comprising a genus of natural or recombinant polypeptides including modified polypeptide sequences, modified by at least one of deletion, addition, insertion and substitution of an amino acid residue in a xylanase amino acid sequence and fragments of same that have not been disclosed in the specification. No description has been provided of all or even a representative number of polypeptide sequences encompassed by the claim. No information, beyond the characterization of SEQ ID NO:2 has been provided by applicants which would indicate that they had possession of the claimed genus of polypeptides. The specification does not contain any disclosure of the structure of all the polypeptide sequences derived from SEQ ID NO:2, including fragments and variants within the scope of the claimed genus. The genus of polypeptides claimed is a large variable genus including peptides which can have a wide variety of structures. Therefore many structurally unrelated polypeptides are encompassed within the scope of these claims. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102/103 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 54-70 are rejected under 35 U.S.C. 102(b) as anticipated by Lischnig et al. (Biotechnology letters, 1993, Vol. 15(4):411-414) or Gomes et al. (Appl. Microbiol. Biotechnol., 1993, Vol. 39:700-707) or Alam et al. (Enzyme Microb. Technol., 1994, Vol. 16, pages 298-302) or Wizani et al. (US 5,183,753, 2-2-1993), or in the alternative, claims 54-71, under 35 U.S.C. 103(a) as obvious over Lischnig et al. or Gomes et al. or Wizani et al. or Alam et al. and Haarasilta et al. (US 5,314,692, 5-24-1994), Hazlewood et al. (WO 93/25693, 12-23-1993). This rejection is based on the public availability of printed document regarding xylanase enzyme.

Claims 54-70 of the instant application are drawn to a xylanase enzyme isolated from *Humicola lanuginosa* (Syn., *Thermomyces lanuginosus*) which has a pH optimum in the range of 4.5-7.5 with a residual activity as disclosed in claim 54 and its use as an animal feed additive. According to applicants own admission, the xylanase enzyme of *Humicola lanuginosa* was known in the prior art as preparations described by Lischnig et al. or Gomes et al. (See page 1, line 28-33) and its use in animal feed (Alam et al. page 2, lines 5-11 of the specification) . Therefore the xylanase enzyme of the instant application anticipates the xylanase enzyme of the reference.

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In the alternative, claims 54-71 would have been obvious for one skilled in the art to use the knowledge existing in the field of enzyme purification, and recombinant techniques at the time the application was filed, to purify the xylanase taught by Wizani et al., Lischinig et al. or Gomes et al. or Alam et al., to homogeneity and use it for making an animal feed or make recombinant DNA or isolate polynucleotides that hybridize to said recombinant DNA under the highly stringent conditions and isolate the encoded xylanase and use it for making an animal feed as in claims 54-70. Wizani et al. also teach a thermostable xylanase enzyme isolated from *T. lanuginosus*. While the references may not teach the testing of the enzyme for residual activity at the temperatures claimed in the instant application, they all teach that the enzyme is thermostable. Furthermore, since the enzyme in the references has been isolated from the very same microorganism as that in the instant application, Examiner takes the position that the enzyme in the reference and the enzyme claimed in the instant application are one and the same and the thermostable characteristics and residual activity characteristics are all inherent features of the enzyme. It would also be obvious to one of ordinary skill in the art to combine the teachings of the above references with the teachings of references such as Haarasilta et al. or Hazlewood et al. and use the xylanase as part of animal feed compositions. The references of Hazlewood et al. and Haarasilta et al. teach the extensive use of xylanase enzymes in food, feed and paper and pulp industry (see the entire reference of Hazlewood et al., specifically pages 20-23). One of ordinary skill in the art would have been motivated to do so as the xylanases taught in the above references are thermostable and would withstand the higher temperatures used in the process of making, storing and transporting the feed. One of ordinary skill in the art would have had a reasonable expectation of success since the art is rich in teachings regarding use of

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xylanase enzyme in the field of food, feed and paper industry. Use of animal feed composition comprising xylanase, for improving the growth of an animal, would also be obvious to one of ordinary skill in the art since the references teach that xylanases digest the complex carbohydrates to simpler and easily digestible materials that become instantly available for the animal. Therefore Wizani et al., Lischinig et al. or Gomes et al. or Alam et al. in combination with Hazlewood et al. or Haarasilta et al. render claims 54-71 *prima facie* to one of ordinary skill in the art.

Applicants may argue that claims are drawn to xylanases that are encoded by polynucleotides which hybridize to nucleotides 31-705 of SEQ ID NO:1 and the references provided by the Examiner fails to provide such sequences. Such an argument would not be persuasive to overcome the rejection because, based on the characteristics of the enzyme in the reference and the instant xylanase, Examiner takes the position that the enzyme in the reference and the instant enzyme are one and the same and the amino acid sequences and polynucleotide sequences that encode them are inherent characteristics. Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594. Furthermore, the decisions handed down in *In re Bell* and *In re Deuel* also does not apply to the above situation. This is because applicants are not claiming polynucleotides encoding the xylanase in which case a reference showing the purified protein would not have rendered the DNA obvious (provided

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applicants had provided a SEQ ID NO for the polynucleotide). However, in the instant case applicants are claiming the a composition comprising the polypeptide and the decisions of *In re Bell* and *In re Deuel* does not apply.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 54-71 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,245,546 B1.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same xylanase enzyme encoded by the same polynucleotide (nucleotides 31-705 of SEQ ID NO:1) and a premix and a process of making animal feed comprising the above xylanase enzyme.

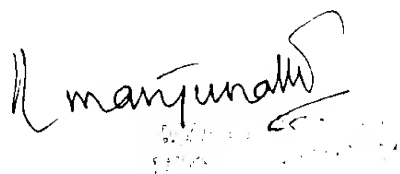
Conclusion

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath Rao whose telephone number is (703) 306-5681. The

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Examiner can normally be reached on M-F from 7:30 a.m. to 4:00 p.m. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, P.Achutamurthy, can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read "Manjunath N. Rao". The signature is stylized with a large initial "M" and a long horizontal stroke extending to the right.

Manjunath N. Rao
Patent Examiner, A.U. 1652
28 February 2003